

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Clopixol 200 mg/ml Solution for Injection** (zuclopenthixol decanoate)

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

1. What Clopixol is and what it is used for
2. What you need to know before you use Clopixol
3. How to use Clopixol
4. Possible side effects
5. How to store Clopixol
6. Contents of the pack and other information

#### **1. What Clopixol is and what it is used for**

Clopixol contains the active substance zuclopenthixol. Clopixol belongs to a group of medicines known as antipsychotics (also called neuroleptics).

These medicines act on nerve pathways in specific areas of the brain and help to correct certain chemical imbalances in the brain that are causing the symptoms of your illness.

Clopixol is used for the treatment of schizophrenia and other related psychoses.

Ask your doctor if you have any questions about why Clopixol has been prescribed for you.

#### **2. What you need to know before you use Clopixol**

##### **Do not use Clopixol**

- if you are allergic to zuclopenthixol or any of the other ingredients of this medicine (listed in section 6). Consult your doctor if you think you might be
- if you have a reduced level of alertness due to the consumption of alcohol or drugs such as opiates (e.g. morphine) and barbiturates
- if you are an older person who suffers from confusion
- if you are receiving emergency treatment to support your blood circulation
- if you are a child.

##### **Warnings and precautions**

Talk to doctor or pharmacist before taking Clopixol if you:

- have a liver problem
- have a history of fits or convulsions or have any condition that might make you prone to fits e.g. head injury, alcohol withdrawal
- are an older person (you may be at risk of low body temperature (hypothermia), sedation, low blood pressure (hypotension) or confusion)
- have Parkinson's disease
- have a narrow angle glaucoma (or a family history of this condition)
- have a respiratory disease (e.g. asthma or COPD (chronic obstructive pulmonary disease))
- have diabetes (you may need an adjustment of your diabetes therapy)
- have an organic brain syndrome (which may be a resulting condition after poisoning with alcohol or organic solvents)
- have risk factors for stroke (e.g. smoking, hypertension)
- have a heart condition, if anyone in your family has a heart condition or if you are taking medicines that change the heartbeat
- have hypokalaemia or hypomagnesaemia (too little potassium or magnesium in your blood)
- suffer from an under or over active thyroid, myasthenia gravis (a condition causing severe muscular weakness) or an enlarged prostate
- are about to undergo any procedure which will require a general anaesthetic (if this is for dentistry, tell your dentist)
- use other antipsychotic medicine
- or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.
- are treated for cancer

Movement disorders such as tremors and muscle spasm may occur, especially during the first few days after initiating therapy. Inform your doctor as the dose may need to be reduced. Inform your doctor if symptoms of a constant urge to move are persistent, as these symptoms can be controlled by the appropriate medication. Inform your doctor if you experience uncontrolled movements of the face and jaw, as therapy discontinuation may be needed.

Difficulty in swallowing may occur as a secondary effect of extrapyramidal symptoms (such as tremors, muscle spasm or movement disorder), sedation (sleepiness), increased salivation, and/or neuroleptic malignant syndrome (a rare dangerous reaction with fever, rigid muscles, changing blood pressure and coma).

### **Children and adolescents**

Clopixol is not recommended in this patient group.

### **Other medicines**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Tricyclic antidepressant medicines (e.g. amitriptyline, imipramine)
- Guanethidine, hydralazine and similar medicines (used to lower the blood pressure)
- Barbiturates and similar medicines (make you feel drowsy)
- Medicines used to treat epilepsy
- Levodopa and similar medicines (used to treat Parkinson's disease)
- Metoclopramide (used in the treatment of gastro-intestinal disorders)

- Piperazine (used in the treatment of roundworm and threadworm infection)
- Digoxin (used in the treatment of heart conditions)
- Corticosteroids (used to treat a range of conditions, including inflammatory diseases)
- Warfarin, ticlopidine, dipyridole and similar medicines called anticoagulants (used to thin the blood)
- Medicines such as diuretics (water tablets) that cause a disturbed water or salt balance (too little potassium or magnesium in your blood)
- Medicines known as non steroidal anti-inflammatory drugs (e.g. ibuprofen, diclofenac, mefenamic acid) and aspirin which are used to relieve pain and to thin the blood)
- Medicines known as phenothiazines used to treat mental illness (e.g. chlorpromazine, fluphenazine).

The following medicines should not be taken with Clopixol:

- Medicines that change the heartbeat such as quinidine, amiodarone, sotalol, dofetilide, erythromycin, terfenadine, astemizole, gatifloxacin, moxifloxacin, cisapride, lithium
- Other antipsychotic medicines (e.g. thioridazine).

### **Clopixol with alcohol**

Clopixol may increase the sedative effects of alcohol making you more drowsy. It is recommended not to drink alcohol during treatment with Clopixol.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you might be pregnant or planning to have a baby, ask your doctor for advice before taking this medicine.

#### **Pregnancy**

If you are pregnant or think you might be pregnant, tell your doctor. Clopixol should not be used during pregnancy, unless clearly necessary.

The following symptoms may occur in newborn babies, of mothers that have used Clopixol in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

#### **Breast-feeding**

If you are breast-feeding, ask your doctor for advice. You should not use Clopixol when breast-feeding, as small amounts of the medicine can pass into the breast milk.

#### **Fertility**

Animal studies have shown that Clopixol affects fertility. Please ask your doctor for advice.

#### **Driving and using machines**

There is a risk of feeling drowsy and dizzy when using Clopixol, especially in the beginning of the treatment. If this happens do not drive or use any tools or machines until these effects wear off.

### **3. How to use Clopixol**

A small volume of Clopixol is drawn up into a syringe and then injected into the muscle of your buttock.

Your doctor will decide on the correct volume of medicine to give, and how often to give it.

The medicine is slowly released from the injection that you receive in your buttock such as a fairly constant amount of medicine gets into your blood between injections.

The recommended dose is:

### **Adults**

The usual dose is 1-3 ml and the interval between injections will usually be 1 to 4 weeks. If your dose is exceeding 2 ml of medicine it will probably be divided between two injection sites.

If you have been treated with Clopixol tablets and you are being transferred to Clopixol injection you may be asked to continue taking the tablets for several days after the first injection.

Your doctor may decide to adjust the amount given, or the interval between injections, from time to time.

### **Older people (above 65 years)**

The dose may be reduced.

### **Patients with special risks**

Your doctor will prescribe a lower dose if you have liver problems.

### **Use in Children and adolescents**

Clopixol is not recommended for children and adolescents.

If you have the impression that the effect of Clopixol is too strong or too weak, talk to your doctor or pharmacist.

### **Duration of treatment**

It is important that you continue to receive your medicine at regular intervals even if you are feeling completely well, because the underlying illness may persist for a long time. If you stop your treatment too soon your symptoms may return.

Your doctor decides the duration of treatment.

### **If you get more Clopixol than you should**

Your medicine will be given by your doctor/nurse.

In the unlikely event that you receive too much Clopixol you may experience some symptoms.

Symptoms of overdose may include:

- Somnolence
- Coma
- Unusual movements
- Convulsions
- Shock
- High or low body temperature
- Changes in the heartbeat including irregular heartbeat or slow heart rate has been seen when Clopixol has been given in overdose together with medicines known to affect the heart.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, Clopixol can cause side effects, although not everybody gets them.

Side effects are most pronounced in the beginning of the treatment and most of them usually wear off during continued treatment:

***If you experience any of the following symptoms contact your doctor or go to the hospital straight away:***

Common (affects 1 to 10 users in 100):

- Racing heart (tachycardia), a sensation of a rapid, forceful, or irregular beating of the heart (palpitations).

Uncommon (affects 1 to 10 users in 1,000):

- Unusual movements of the mouth and tongue; this may be an early sign of a condition known as tardive dyskinesia.

Rare (affects 1 to 10 users in 10,000):

- Hypersensitivity, acute systemic and severe allergic reaction (anaphylactic reaction). Most anaphylactic reactions involve the skin with development of hives, generalized redness and swelling of face, eyelids, lips, tongue, throat, hands and feet. Other symptoms could be difficulty breathing, wheezing, chest tightness, rapid heart beat, dizziness and loss of consciousness. The symptoms of anaphylactic reaction can vary. In some people, the reaction begins very slowly, but in most the symptoms appear rapidly and abruptly.
- Low blood platelet count (thrombocytopenia). A common symptom is bruising of the skin. Reduced white blood cell count (neutropenia, leukopenia). Symptoms could be increased frequency of infections. Severe reduction in number of white blood cells which makes infections more likely (agranulocytosis).
- Persistent, painful erection of the penis unaccompanied by sexual excitation or desire (priapism).
- Difficulty in swallowing (see section 2).

Very rare (affects less than 1 user in 10,000):

- High fever, unusual stiffness of the muscles and disorder of your consciousness, especially if occurring with sweating and fast heart rate; these symptoms may be signs of a rare condition called neuroleptic malignant syndrome which has been reported with the use of different antipsychotics.
- Yellowing of the skin and the white in the eyes, this may mean that your liver is affected and a sign of a condition known as jaundice.
- Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing.

***The following side effects have also been reported:***

Very common (affects more than 1 user in 10):

- Sleepiness (somnia), inability to sit still or remain motionless (akathisia), involuntary movements (hyperkinesia), slow or diminished movements (hypokinesia)
- Dry mouth.
- Movement disorder (Extrapyramidal symptoms) – due to effects on a part of the brain that regulates movements which may result in tremors, muscle spasms or movement disorders (see section 2).

Common (affects 1 to 10 users in 100):

- Tremor, twisting or repetitive movements or abnormal postures due to sustained muscle contractions (dystonia), increased muscle stiffness (hypertonia), dizziness, headache, sensation of tingling, pricking or numbness of the skin (paraesthesia), disturbance in attention, amnesia, gait abnormal
- Difficulties focusing on objects near to the eye (accommodation disorder), vision abnormalities
- Sensation of spinning or swaying while the body is stationary (vertigo)
- Blockage of the nasal passages (nasal congestion), difficulty breathing or painful breathing (dyspnoea)
- Increased saliva secretion (salivary hypersecretion), constipation, vomiting, digestive problems or discomfort centred in the upper abdomen (dyspepsia), diarrhoea
- Urination disorder (micturition disorder), lack of ability to urinate (urinary retention), increased urination volume (polyuria)
- Increased sweating (hyperhidrosis), itching (pruritus)
- Muscle pain (myalgia)
- Increased appetite, increased weight
- Fatigue, weakness (asthenia), general feeling of discomfort or uneasiness (malaise), pain
- Sleeplessness (insomnia), depression, anxiety, nervousness, abnormal dreams, agitation, decreased sexual drive (libido decreased).

Uncommon (affects 1 to 10 users in 1,000):

- Overactive or over responsive reflexes (hyperreflexia), jerky movements (dyskinesia), parkinsonism, fainting (syncope), inability to coordinate muscle activity (ataxia), speech disorder, decreased muscle tone (hypotonia), convulsion, migraine
- Circular movement of the eye (oculogyration), dilated pupils (mydriasis)
- Over-sensitivity to certain frequency ranges of sound or difficulty tolerating everyday sounds (hyperacusis), ringing in the ears (tinnitus)
- Abdominal pain, nausea, flatulence
- Rash, skin reaction due to sensitivity to light (photosensitivity reaction), pigmentation disorder, greasy, shiny and yellowish skin due to increased secretion of sebum (seborrhoea), eczema or inflammation of the skin (dermatitis), bleeding underneath the skin seen by red or purple discolorations on the skin (purpura)
- Muscle rigidity, inability to normally open the mouth (trismus), twisting of the neck and an unnatural position of the head (torticollis, wryneck, stiff neck)
- Decreased appetite, decreased weight
- Low blood pressure (hypotension), hot flush
- Thirst, abnormally low body temperature (hypothermia), fever (pyrexia)
- Red or sore skin where the Clopixol injection was given
- Abnormal liver function tests
- Sexual disturbance (delayed ejaculation, problems with erection, women may experience failure to achieve an orgasm, vaginal dryness (vulvovaginal dryness))

- Pronounced indifference to one's surroundings (apathy), nightmare, increased sexual drive (libido increased), state of confusion.

Rare (affects 1 to 10 users in 10,000):

- High blood sugar (hyperglycaemia), impaired glucose tolerance, increased blood fat levels (hyperlipidaemia). Often there are no symptoms. Hyperglycaemia over long time could show as fatigue, weight loss, excessive thirst and urination.
- Increased level of prolactin in the blood (hyperprolactinaemia). Symptoms of hyperprolactinaemia could be excessive milk production (galactorrhoea), lack of menstrual periods (amenorrhoea) and development of breasts in men (gynaecomastia).

As with other medicines that work in a way similar to zuclopenthixol decanoate (the active ingredient of Clopixol), rare cases of the following side effects have been reported:

- QT prolongation (slow heart beat and change in the ECG)
- Irregular heart beat (ventricular arrhythmias, ventricular fibrillation, ventricular tachycardia)
- Torsades de Pointes (a special kind of irregular heart beat).

In rare cases irregular heart beats (arrhythmias) may have resulted in sudden death.

In older people with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.

If you stop taking Clopixol too quickly, you may experience discontinuation symptoms. The most common symptoms are feeling sick (nausea), being sick (vomiting), anorexia, loose stools (diarrhoea), runny nose (rhinorrhoea), sweating, pains in the muscles (myalgias), feelings like pins and needles (paraesthesias), sleeplessness (insomnia), restlessness, anxiety and agitation. You may also experience dizziness (vertigo), alternate feelings of warmth and coldness, and shakiness (tremor). The symptoms usually begin within 1 to 4 days of stopping Clopixol and go away within 7 to 14 days. If you get severe discontinuation symptoms, contact your doctor for advice.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

**Ireland**

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

**Malta**

ADR Reporting

Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Clopixol**

Usually your doctor or nurse will store this medicine for you.

If you keep it at home:

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Keep the ampoules in the outer carton in order to protect from light.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Clopixol contains**

The active substance is zuclopenthixol decanoate.

Each millilitre (ml) of Clopixol contains 200 mg of zuclopenthixol decanoate.

The other ingredient is thin vegetable oil (triglycerides, medium chain).

### **What Clopixol looks like and contents of the pack**

Clopixol 200 mg/ml solution for injection (injection) is presented in colourless glass ampoules containing 1 ml (200 mg).

The 1 ml ampoule is available in boxes of 10 ampoules.

Clopixol is a clear pale-yellow liquid.

### **Marketing Authorisation Holder**

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